

II. Information Disclosure Statement

At page 2 of the Office Action, the Examiner indicated that the Information Disclosure Statement filed November 10, 2003, failed to comply with 37 C.F.R. § 1.98(a)(1) because Form 1449 was missing. In response, Applicant has concurrently filed an Information Disclosure Statement, with an attached Form PTO/SB/08, providing an updated list of documents in compliance with 37 C.F.R. § 1.98(a)(1). Applicant has also paid the appropriate fee to have the Information Disclosure Statement considered at this time. Accordingly, Applicant respectfully requests consideration of the documents cited.

III. Claim Rejections - 35 U.S.C. § 103(a)

A. *Claims 39-42 and 44 - Armini*

The Examiner has rejected claims 39-42 and 44 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,919,126 (“Armini”). Office Action at 2. Applicant respectfully disagrees and traverses this rejection for at least the following reasons.

To establish a *prima facie* case of obviousness, the prior art reference must teach or suggest all the claim limitations. M.P.E.P. § 2143. Armini neither teaches nor suggests all the claim limitations, and thus fails to render the claimed invention obvious.

Independent claim 39 recites, *inter alia*, a laminate stent comprising “a substrate tube formed from a superelastic alloy...” In contrast, Armini discloses that its stent can be made from “structural material such as titanium, stainless steel, nitinol alloy or any other stiff alloy...” See Armini at col. 5, lines 45-48. Armini does not teach or suggest that its stent can be made using a non-stiff alloy, much less an elastic or superelastic alloy. It is well-known that superelastic alloys comprise alloy compositions that exhibit a useful manifestation of the shape

memory effect achieved through processing techniques, such as cold working and annealing. *See, e.g.*, U.S. Patent No. 4,896,955 at col. 1, line 36 to col. 2, line 18 and col. 4, line 39 to col. 6, line 4 (“Zider”); Duerig et al., “An Engineer’s Perspective of Superelasticity,” *Engineering Aspects of Shape Memory Alloys* at pages 369 and 382-392 (“Duerig”). Such processing imparts properties that can vary widely depending on the exact processing used. *See* Zider at col. 4, lines 39-42; Duerig at page 369 and 382-392. As one skilled in the art would readily appreciate, there is a significant difference in the properties of the resulting superelastic alloys as compared to alloys having similar compositions that have not been accordingly treated. *See* Zider at col. 1, line 36 to col. 2, line 18; Duerig at page 369. Thus, one skilled in the art would clearly appreciate that Armini’s teaching of nitinol as an equivalent to stainless steel and titanium, neither of which are disclosed as even possibly processed to exhibit superelastic properties, and which conversely rely on the material’s stiffness properties, neither teaches nor suggests the use of superelastic alloys as a substrate for a laminate stent.

Claim 39 further recites that the cylindrical elements and the interconnecting elements are “entirely formed of the substrate tube, the first cladding layer, and the second metallic radiopaque cladding layer.” As the Examiner acknowledges, “Armini does not disclose the stent having interconnecting element connection adjacent cylindrical elements as claimed.” Office Action at 2. Nevertheless, the Examiner alleges that the interconnecting elements are well known in the art and “would have been obvious matter [sic] of design choice.” Office Action at 2. However, neither Armini nor any of the prior art of record teaches or suggests a stent having “cylindrical elements interconnected by elements disposed between adjacent cylindrical elements,” as recited in claim 39. As the M.P.E.P. states, “[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where

there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.” *See* M.P.E.P. § 2143.01.

As is apparent, there is no motivation in the prior art, nor has the Examiner provided any, to provide a stent wherein the cylindrical elements and the interconnecting elements are “entirely formed of the substrate tube, the first cladding layer, and the second metallic radiopaque cladding layer,” as recited in claim 39. Accordingly, Armini does not teach or suggest all of the limitations recited in the presently pending claims. The prior art furthermore fails to provide any motivation to modify the stent disclosed in Armini. Applicant therefore respectfully requests the withdrawal of this rejection under 35 U.S.C. § 103(a) for at least the foregoing reasons.

B. Claim 43 - Armini in view of Delfino

The Examiner has rejected claim 43 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,919,126 (“Armini”) in view of U.S. Patent No. 6,264,595 (“Delfino”). Office Action at 3. Applicant respectfully disagrees and traverses this rejection for at least the following reasons.

Initially, Delfino fails to cure the deficiencies of Armini, as identified above, and for at least this reason, the rejection of claim 43 is unsubstantiated, and thus improper.

Furthermore, claim 43 recites a first cladding layer that comprises “a metal selected from the group consisting of stainless steel, nickel-cobalt-chromium-molybdenum alloy and chonichrome.” The Examiner alleges that Delfino discloses a “first cladding layer being stainless steel,” and that it would have been obvious to one skilled in the art “to use stainless steel as the transition layer or adhesion layer for Armini’s stent wherein doing so would amount

to mere substitution of one material for an other [sic] within the same art that would perform equally well in Armini's stent." Office Action at 3. Applicant respectfully disagrees.

As is apparent to the skilled artisan, Delfino does not teach a cladding layer. The stainless steel referred to by the Examiner is the stent substrate itself to which a radioactive compound (e.g., ^{32}P) is bound. *See, e.g.*, "Example 1," Delfino at col. 6, lines 40. Thus, Delfino neither teaches nor suggests the use of "a first cladding layer formed from a metallic material and bonded to the exterior surface of the substrate tube."

Accordingly, for the reasons presented above detailing the insufficient teachings of Armini, as well as the failure of Delfino to cure those deficiencies, the combination of Armini and Delfino does not teach or suggest all of the limitations recited in the presently pending claims. Therefore, Applicant respectfully requests withdrawal of this rejection under 35 U.S.C. § 103(a) for at least the foregoing reasons.

C. *Claims 39-43 - Delfino*

The Examiner has rejected claims 39-43 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,264,595 ("Delfino"). Office Action at 3. Applicant respectfully disagrees and traverses this rejection for at least the following reasons.

To establish a *prima facie* case of obviousness, the prior art reference must teach or suggest all of the claim limitations. M.P.E.P. § 2143. Delfino fails to teach or suggest all the claim limitations, and thus cannot render obvious the presently claimed invention.

As explained above, Delfino does not teach a stent having any cladding layers. Delfino discloses a transition metal stent (e.g., stainless steel) which has a radioisotope chemically bonded to the transition metal stent surface. Delfino at col. 5, lines 12-17. Delfino neither teaches nor suggests the use of a cladding layer within its stent.

Furthermore, Delfino neither teaches nor suggests a stent having “a substrate tube formed from a superelastic alloy” or a stent pattern including “a plurality of radially expandable cylindrical elements disposed generally coaxially and interconnected by elements disposed between adjacent cylindrical elements,” as recited in claim 39.

Therefore, Applicant respectfully requests the withdrawal of the rejection under 35 U.S.C. § 103(a) for at least the foregoing reasons.

IV. Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Attachments:

U.S. Patent No. 4,896,955.

Duerig et al., “An Engineer’s Perspective of Superelasticity,” Engineering Aspects of Shape Memory Alloys, 369-393 (1990).